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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,211	08/24/2001	Daniel Lootz	7040-40	3319
21324	7590	07/08/2004	EXAMINER	
HAHN LOESER & PARKS, LLP TWIN OAKS ESTATE 1225 W. MARKET STREET AKRON, OH 44313			THALER, MICHAEL H	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,211

Applicant(s)

LOOTZ ET AL. *ml*

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8-10,12-21,24,44,64,67,70,71,74-78,81,82,85,86,89,90,93-95,99-101 and 105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,5,6,8-10,12-21,24,44,64,67,70,71,74-78,81,82,85,86,89,90,93-95,99-101 and 105.

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 19, 2004 has been entered.

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Holder 10 appears to be located only at the distal portion of the catheter. It is unclear from the disclosure how holder 10 is manipulated (either by being held stationary or by moving it) from the proximal end of the catheter. No such means is shown in the drawings.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Claim 24 is confusing and inaccurate since the device for producing relative movement of the sheathing device in the first direction is defined as being different from the device for producing relative movement of the sheathing device in the second direction. However, it appears from the disclosure that this is not the case. In fact, it is not understood how there could be two separate devices.

Claims 1, 5, 6, 8-10, 12-15, 24, 44, 64, 67, 70, 71, 74-77, 81 and 105 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Duerig et al. (6,190,406). Duerig et al. disclose a plurality of annular support portions 52 comprising bar elements 60 and connecting bars 70, wherein the connecting bars 70 engage in a region of the bar elements of the first annular support portion that projects in the longitudinal direction (in the embodiment described in col. 5, lines 46-53 in which one end is attached to the strut rather than the loop, noting that the entire strut projects in the longitudinal direction particularly in view of [0060] of applicant's specification which indicates that a portion of the bar element "projects less far in the first direction") and wherein the

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connecting bars engage a central portion of the second annular support portion (in the embodiment described in col. 5, lines 46-53 in which the other end is attached to the strut rather than the loop). Alternatively, it would have been obvious that the connecting bars 70 engage in a region of the bar elements of the first annular support portion that projects in the longitudinal direction for the reasons set forth above. As to claim 5, in the embodiment described in col. 5, lines 46-53 in which one end of the connecting bar 70 is attached to the strut rather than the loop, the connecting bars 70 engage the strut "near a turning point" as claimed since "near" is a relative term and any point on the strut is "near a turning point" as compared to other portions of the stent, for example. As to claim 6, Duerig et al. disclose an embodiment in which one end of the connecting bar 70 is attached to a strut and the other end is attached to a loop, noting the term "and/or" in reference to each end of the connecting bar in the phrase "wherein one end is attached to one strut and/or loop, and another end attached to a strut and/or loop on an adjacent hoop" in col. 5, lines 46-53. In this embodiment, the end of the connecting bar 70 that is attached to a loop "engages a point that projects furthest

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in the longitudinal direction" as claimed, since figures 4 and 4a show the end of the connecting bar 70 attached to a loop at a point which projects furthest in the longitudinal direction even though it is attached slightly off center to the apex of the loop. In any event, the "point that projects furthest in the longitudinal direction" is considered to be the "turning point" which is considered to be the entire curved portion near the apex. As to claims 10 and 105, note col. 7, lines 39-60 of Duerig et al. As to claim 24, Duerig et al. disclose a device 22 for holding the stent during relative movement between the sheathing device and the stent.

Claims 16-18, 78, 82, 85, 86, 89, 90, 94, 95, 100 and 101 rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406). As to claim 16, for example, Duerig et al. fail to disclose the stent material in a stress-induced martensitic state at body temperature. However, it is old and well known in this art to design make shape memory alloys such that they are in a stress-induced martensitic state at body temperature in order to facilitate entry into the patient's body. It would have been obvious to make the Duerig et al. the stent material in a stress-induced martensitic state at body temperature

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so that it too would have this advantage. The above well known in the art statement is taken to be admitted prior art because applicant failed to traverse the examiner's assertion (M.P.E.P. 2144.03). As to claims 18, 85, 86 and 90, the width of the Duerig et al. bar element varies over the length thereof (col. 6, lines 8-39). As to claims 94 and 100, the center line of the Duerig et al. bar element is in the shape of an elliptical arc in the region of the turning points when the stent is expanded, as seen in figure 5, for example.

Claims 19-21, 93 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (6,190,406) in view of Lau et al. (6,015,429). Duerig et al. fail to disclose a direction of curvature changing in the central region of the bar element. However, Lau et al. teach that the central region of a meandering bar element of a stent may be curved (at 114 in figure 1C) instead of straight (at 106 in figure 1A). This shape has the self-evident advantage of providing more support to the blood vessel along the edges of the meandering bar element. It would have been obvious to incorporate this shape into the Duerig et al. bar element so that it too would have this

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advantage. Note that the direction of curvature changes at 114 in figure 1C.

Applicant's arguments filed April 19, 2004 have been fully considered but they are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
7/1/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731